

represented to contain 2 grains of maleic acid; whereas each tablet contained less than 2 grains, namely, not more than 1.39 grains, of maleic acid.

On March 2, 1938, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

W. R. GREGG, *Acting Secretary of Agriculture.*

**28685. Adulteration and misbranding of gauze bandage. U. S. v. 48 Dozen Packages of Gauze Bandage. Tried to the court and a jury. Jury excused before verdict. Judgment of condemnation and destruction. Affirmed by circuit court of appeals. (F. & D. No. 37890. Sample No. 72823-B.)**

This article was not sterile, as represented on the label.

On July 14, 1936, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 48 dozen packages of gauze bandage at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about May 15, 1936, from Bridgeport, Conn., by the Bay Co., and charging adulteration and misbranding in violation of the Food and Drugs Act.

The article was alleged to be adulterated in that its purity fell below the professed standard and quality under which it was sold, namely, on the carton "Sterilized," and in that it was not sterilized but did contain anaerobic bacteria and gram-positive and gram-negative bacilli capable of growing under aerobic conditions.

It was alleged to be misbranded in that the statement appearing on the package, "Sterilized," was false and misleading in that the article was not sterilized.

The Bay Co., of Bridgeport, Conn., having filed an answer, the case was tried before the court and a jury, on April 13, 14, and 15, 1937. A motion for a directed verdict was then made by each of the parties. Whereupon, a jury verdict was waived, the jury was discharged and decision of the issues was reserved by the court. On May 27, 1937, the court rendered the following opinion:

*INCH, District Judge:* "The United States duly commenced the above entitled action whereby the condemnation is sought of a quantity of gauze bandages manufactured by the Bay Company of Bridgeport, Connecticut, and shipped by it from that state, in interstate commerce, to New York City, where they were seized in the possession of Parke, Davis & Company, New York City, State of New York.

"The action is brought pursuant to the provisions of the Federal Food and Drugs Act of June 30, 1906 (34 Stat. L. 768, as amended, 37 Stat. L. 316, 732). There is no question as to jurisdiction. Many of the essential facts are admitted.

"The Bay Company duly filed a claim to the merchandise and likewise filed an answer to the libel, in this it denies that 'bandages' are within the definition of a 'Drug,' as defined in the statute in question. It also denies that the bandages are 'adulterated' or 'misbranded.'

"The above issues duly came on for trial before a jury and both sides later moved for a directed verdict. The court thereupon reserved decision, the jury was excused, and the duty now rests upon the court to make proper findings and decision in the place of a verdict.

"While, unless duly agreed to, any statement by the court in this decision as to facts for the purpose of presentation of its decision is not to be considered as taking the place of findings, nevertheless, it is necessary that the court state at the outset what it believes these facts to be.

"These facts briefly are that on or about May 15, 1936, the Bay Company manufactured and shipped to Parke, Davis & Company approximately 48 dozen packages of gauze bandages. These bandages were contained in cartons, each of which contained a dozen bandages, these individual bandages, in turn, being enclosed in separate cartons.

"The label on the large carton containing the dozen packages is as follows:

	One Dozen	
4		10
Inches		Yards
	Bay's	
	Gauze Bandages	
Absorbent		Sterilized
	The Bay Company	
	Bridgeport, Connecticut	
	A Division of	
	Parke, Davis & Co.	

"The label on the individual carton containing the single bandage, plainly for the information and guidance of the customer, is as follows:

Bay's

Gauze

Bandage

Guarantee

This Bay Product Has Been Scientifically Prepared For  
Surgical Use Under Most Sanitary Manufacturing  
Conditions.

(Bay Bandage)

Absorbent

Sterilized

Non-Ravel

The Quality Must Be Satisfactory To You, Or Your  
Dealer Will Make Full Price Refund.

"It will be seen therefore that the Bay Company, in this manner, claimed that the gauze bandage not only had been 'sterilized' but was for 'surgical use.'

"On June 17, 1936, the Government duly obtained proper samples of this merchandise and had same examined by bacteriologists of the Food and Drug Administration. This examination revealed evidence in the bandage of living bacterial growth of the three subdivisions of bacteria, classified by witnesses as gram-positive and gram-negative bacteria of aerobic and anaerobic character.

"Thereupon, and on or about July 14, 1936, the Government commenced this action seeking the condemnation of these bandages, under the provisions of Section 10, of the said Act, claiming that the bandages were not 'sterilized' and were therefore 'misbranded' and 'adulterated.'

"Subsequently, on October 14, 1936, a further sample was taken pursuant to an order of the court with the same result as in the first examination.

"The Government has proved that these bandages so seized were not 'sterilized.' That the statement on the cartons that they were so 'sterilized' is false. The accepted definition of 'sterilization' means that all bacteria are absent in a sterilized bandage. That it is free from all living micro-organisms.

"It may well be that the well known and long established concern into whose possession these bandages came, and where they were seized, is as much concerned with the proper enforcement of law in regard to pure drugs, etc., as anyone else, but this controversy is not over a claim that an 'unsterilized' bandage is as safe as a 'sterilized' bandage, but whether the law in question applies to any bandage. It is beside the point that some individual, misled by a false advertisement may have a right to redress a wrong occasioned by such false statement on which reliance was properly had.

"In the light of modern knowledge it no longer needs any argument to say that the difference between a 'sterilized' bandage and an 'unsterilized' bandage is extremely important in its use by surgeons and physicians. No doctor nowadays would think of knowingly applying an 'unsterilized' bandage to an open wound. The general education of the public is such that it can be safely said that the average layman would not do so either. The necessity for protection of the public arises from such fact with its far reaching consequences.

"Sufficient therefore has been said to indicate the importance of the subject we are considering, and the necessity for protecting legislation in regard to the general welfare of the citizens of this country.

"This brings us to the real issue whether or not the Congress has in fact legislated on this subject of bandages with sufficient clearness so that the court can hold that the law in question plainly forbids manufacturing and selling these 'unsterilized' bandages as 'sterilized' bandages and as fit 'for surgical use.'

"The claimant, while disputing the importance of the subject, nevertheless claims that the Congress has not yet so legislated.

"If claimant is right, the court cannot usurp the legislative function however great the temptation. Its function is to interpret the law not to make it. Thereafter the proper legislative body may amend or substitute or modify to meet the defect found by such interpretation.

"We will now consider this statute. It is the so-called Federal Food and Drugs Act, of June 30, 1906, as amended, etc. (Title 21, U. S. C.) of which so far as applicable, Section 1 is as follows:

"'Adulterated or misbranded foods or drugs; manufacture in Territories or District of Columbia unlawful; penalty. It shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of sections 1 to 15, inclusive, of this title; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor.'

"Section 7 so far as applicable is as follows:

"7. Same; "drug and food." The term "drug," as used in sections 1 to 15, inclusive, of this title, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used in said sections, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound. (June 30, 1906, c. 3915, 6, 34 Stat. 769)."

"Sections 9 and 10 so far as applicable are as follows:

"9. Misbranded; meaning and application. The term "misbranded," as used in sections 1 to 15, inclusive, of this title, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced. (June 30, 1906, c. 3975, 8, 34 Stat. 771; Aug. 23, 1912, c. 352, 37 Stat. 416; Mar. 3, 1913, c. 117, 37 Stat. 732).

"10. Misbranded articles. For the purpose of sections 1 to 15, inclusive, of this title, an article shall be deemed to be misbranded; Drugs. In case of drugs: Imitation or use of name of other article.—First. If it be an imitation of or offered for sale under the name of another article. Removal and substitution of contents of package, or failure to state on label quantity or proportion of narcotics therein. \* \* \* Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent."

"14. Seizure of articles upon discovery for condemnation; disposition; delivery to owner on bond; proceedings. Any \* \* \* drug \* \* \* that is adulterated or misbranded within the meaning of sections 1 to 15, inclusive, of this title, and is being transported from one State, Territory, District, or insular possession to another for sale, \* \* \* shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation."

"Claimant argues that a gauze bandage is not 'any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.' It is its contention that as these above-quoted words follow the words 'all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary,' they are thereby limited. That they are meaningless standing alone for otherwise 'they are broad enough to include everything from plaster casts, spectacles, to braces and crutches.' Therefore, says claimant, by the doctrine of ejusdem generis the first mentioned general words will be held to include only such things as are of the same kind as those enumerated in the last mentioned group. The Government claims that this is improperly limiting such an important statute, that, even so, absorbent cotton, adhesive plaster, are among preparations recognized in the United States Pharmacopoeia.

"The Congress, in the Act now before us, does confine the words 'any substance or mixture of substances, etc.,' to substances 'used for the cure, mitigation or prevention of disease.' Such only are to be considered under its definition of the word 'Drug.'

"Surely the bandages here seized were 'substances.' As to whether the bandages here seized were to be used 'for the cure, mitigation, or prevention of disease' we have substantial and uncontradicted evidence in the record from recognized medical authorities, to the effect that they are so used when 'sterilized.'

"Doctor Klumpp used gauze bandages to hold dressings on a wound also as a packing within the wound. 'In certain diseases there are wounds which are part of the disease. They must be treated with gauze in order to cure the disease.'

"Doctor Paulonis: 'Gauze bandages are frequently used in the cure of disease.'

"Doctor Lippold 'used bandages as drains in infected wounds.'

"Doctor Leonard testified he has used gauze bandages on numerous occasions in the cure of the disease as in the case of burns and drains, and to prevent hemorrhage.

"The testimony sufficiently indicates that no surgeon or physician would think of using an 'unsterilized bandage' in such cases.

"As I have said, all this testimony by the surgeons, nurses, and physicians relates to a 'sterilized' bandage, but the bandages here in question were claimed to be such and to be prepared for surgical use.

"It may be possible to argue that the present law does not cover 'any bandage' and that the Congress is now considering a definition of 'Drug' that will cover same, but we are not concerned here with 'any bandage.' We are concerned with a bandage that purports to be 'sterilized' and 'prepared for surgical use.' The claimant cannot escape from its own words and this deliberate choice and offer to the public.

"The primary purpose of the statute is to prevent injury to the public health. *U. S. vs. Lexington* 232 U. S. 399, *Savage vs. Jones* 225 U. S. 501. *McDermott vs. Wisconsin* 228 U. S. 115. *U. S. vs. Coca-Cola* 241 U. S. 265.

"It is the duty of the court to give a sensible construction to this statute in order, if possible, to accomplish the legislative intent. *Hawaii vs. Mankichi* 190 U. S. 197.

"A 'sterilized' bandage is a well recognized substance used by surgeons and physicians in cases of, the cure of, the prevention of, disease as testified to by experts in this record. The Congress surely intended to exclude from interstate commerce an impure and misbranded bandage pretending to be 'sterilized' and 'prepared for surgical use,' and prevent it from being transported from the manufacturer to people who might reasonably use them. It seems to me that any other interpretation is impossible in the light of the express purpose of the Congress. *Hipolite, etc., vs. U. S.* 220 U. S. 45.

"If the brand or label deceives, it is sufficient basis for holding that it is a misbrand. *U. S. vs. 95 Barrels* 265 U. S. 438. The statute defines what is 'adulterated.'

"It is sufficiently plain that the bandages thus offered to the public were claimed to have been 'sterilized' and 'scientifically prepared for surgical use.' The choice of such words cannot be considered inadvertent. On the contrary, claimant has specifically intended the bandages to be for surgical use which certainly means that they are substances or materials intended to be used by a surgeon in connection with his surgery to protect a patient from the evident danger of infection arising from the use of an 'unsterilized' bandage.

"If this is so then the present statute sufficiently covers such danger to public health and the Government was right in seizing these bandages so claimed to have been 'sterilized' and 'prepared for surgical use,' on the ground that the label is false, misleading, and that the bandage is misbranded. The bandages likewise fall below the professed standard of quality under which they were sold and therefore are adulterated.

"Accordingly, the Government is entitled to judgment with costs. Submit findings."

On July 1, 1937, judgment of condemnation was entered and the court ordered the issuance of a writ of destruction.

On July 12, 1937, notice of appeal and assignments of error having been filed by the claimant, petition for appeal from that judgment to the Circuit Court of Appeals for the Second Circuit was granted. On February 7, 1938, the Circuit Court of Appeals handed down the following decision affirming the judgment of the district court:

CHASE, *Circuit Judge*: "The United States seized, and then filed its libel in the District Court for the Eastern District of New York to have condemned and declared forfeited, 48 packages of plain gauze bandages under the provisions of the Pure Food and Drugs Act (37 Stat. Secs. 416, 732; 21 U. S. C. A.). The appellant appeared as claimant and answered. On issue joined, the cause came on for trial by jury but both parties moved for a directed verdict and then waived the jury. The court then made findings of fact and entered the judgment from which the claimant has appealed.

"The findings of fact show that on or about May 19, 1936, the claimant shipped the packages of gauze bandages which were later seized and condemned from Bridgeport, Conn., to Parke, Davis & Co., in New York City. Except for samples which have been removed, all the gauze is now in the custody of the United

States marshal for the Southern District of New York. The claimant is the owner.

"The gauze was in small packages contained in larger cartons which were labeled, as were the small packages, to the effect that the gauze was sterilized. Each small package also bore a guaranty stating in part that 'This Bay product has been scientifically prepared for surgical use under the most sanitary manufacturing conditions.'

"The gauze was not, however, sterilized or fit for surgical use but did contain 'living bacteria consisting of gram-positive sporeforming bacilli and nonspore-forming bacilli, gram-positive and gram-negative bacilli, capable of growing aerobic conditions and anaerobic bacteria.' And it was a substance intended for use in the cure, prevention, and mitigation of disease in man.

"The turning point of decision on this appeal is whether such a substance as this gauze bandaging is within the scope of the Pure Food and Drugs Act and so subject to seizure and forfeiture. If it is within the Act at all, it must fall within its purview as a 'substance \* \* \* intended to be used for the cure, mitigation, or prevention of disease of either man or other animals' defined to be a 'drug' in 21 U. S. C. A. Sec. 7. That it was, indeed, a substance is self evident and the above finding as to its intended use certainly brings it within the broad language of the statutory definition of a 'drug.' But it is argued that such broad definition must be held to be somewhat narrowed, under the principle of ejusdem generis, by words used in the statute in connection with it and with that contention we are fully in accord. The complete statutory definition of drug is as follows:

"The term 'drug' as used in sections 1 to 15, inclusive, of this title, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. (21 U. S. C. A. Sec. 7.)

"But the application of the principle for which the claimant contends does not help its cause in this particular instance. Among those things recognized in the United States Pharmacopoeia as 'preparations' are absorbent cotton and adhesive plaster made by spreading the adhesive on cotton cloth. But we need not place any emphasis upon adhesive plaster, however, for the recognition in the pharmacopoeia of absorbent cotton, a substance generally similar in composition and use to a gauze bandage, sufficiently shows that the latter, while not itself recognized, is of a kind with what is. That makes it exactly the sort of thing Congress must have intended to include in the general language which was, of course, put there for the very purpose of making the statute cover more substances of the kind mentioned than were actually recognized in the Pharmacopoeia or National Formulary.

"The Act was passed to prevent injury to the public health. *United States v. Lexington Mill and Elevator Co.*, 232 U. S. 399. It should be given a fair and reasonable construction to attain its aim. These bandages, clearly intended for surgical use, are certainly a menace to the public health when misbranded to show that they were sterilized. They were not fit for the use for which their labels falsely represented them to have been prepared and so were subject to condemnation and forfeiture. *United States v. 95 Barrels of Vinegar*, 265 U. S. 438.

"Judgment affirmed."

W. R. GREGG, *Acting Secretary of Agriculture.*

**28686. Misbranding of Kalo's Veterinary Salve and Kalo's Headache Powders.**  
*U. S. v. Mentho Jell Co., Inc. Plea of guilty. Fine, \$25. (F. & D. No. 39501. Sample Nos. 5077-C, 19579-C.)*

The labeling of both these products bore false and fraudulent therapeutic and curative claims, and that of the headache powders contained an incorrect declaration of the amount of acetanilid contained in them.

On January 18, 1938, the United States attorney for the District of Minnesota, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Mentho Jell Co., Inc., Albert Lea, Minn., alleging shipment by the said corporation in violation of the Food and Drugs Act as amended, on or about May 27 and August 24, 1936, from the State of Minnesota into the State of Iowa of quantities of Kalo's Veterinary Salve and Kalo's Headache Powders which were misbranded. The articles were labeled in part: "Mentho Jell Co., Albert Lea, Minnesota."

Analyses showed that the veterinary salve consisted of a dark yellow aromatic